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# TRANSMITTAL FORM

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Total Number of Pages in This Submission

Application Number	09/997633- <b>663</b>
Filing Date	November 29, 2001
First Named Inventor	Lorraine Faxon Meisner
Art Unit	1616
Examiner Name	F. Choi
Attorney Docket Number	41758/P001P2X1

## ENCLOSURES (Check all that apply)

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Remarks

The attached Amended Appeal Brief is filed in triplicate.

Applicant claims small entity status. A check in the amount of \$250.00 was paid in the original filing of the Appeal Brief on December 2, 2005. Any excess of insufficiency should be credited or debited to Deposit Account No. 23-2426.

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Winstead Sechrest & Minick, P.C.		
Signature	<i>Carol M. Nielsen</i>		
Printed name	Carol M. Nielsen		
Date	<i>January 5, 2006</i>	Reg. No.	37,676

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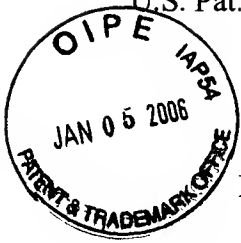
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U.S. Pat. App. Ser. No. 09/997,663

Atty. Docket No. 41758/P001P2X1

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

**Group Art Unit:** 1616 )  
 )  
**Examiner:** F. Choi )  
 )  
**Applicants:** Meisner, Lorraine Faxon )  
 )  
**Application Number:** 09/997,663 )  
 )  
**Filed:** November 29, 2001 )  
 )  
**For:** COMPOSITIONS AND METHODS )  
 FOR THE TREATMENT SKIN )

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**AMENDED APPEAL BRIEF**

Appellant appeals from the rejections of claims 1, 5-8, 10-16, 18-19 dated May 11, 2005  
in the above-identified patent application.

The fee of \$250 as required under § 41.20 (2) was paid in the original filing of the brief  
on December 2, 2005.

**Real Parties In Interest**

The real party in interest is Bioderm, Inc., the assignee of the entire right and interest in the present application.

**Related Appeals and Interferences**

There are no other related appeals and/or interferences pending.

**Status of Claims**

The application was filed with original claims 1-20. Claims 2, 3, 4, 9, 17 and 20 are to be cancelled. Claims 1, 5-8, 10-16, 18-19 stand rejected. Claims 1, 5-8, 10-16, 18-19 are being appealed.

**Status of Amendments**

An amendment to the claims was filed on December 1, 2005 after Office Action Mailed May 11, 2005 and before the filing of this brief. In amendment, cancellation of claims 3, 4, and 17 is requested. Amendment of claims 11 and 19 is also requested.

**Summary of Claimed Subject Matter**

Independent claim 1, upon which claims 5 through 8, 10 through 16 depend and claim 19 which depends on claim 13, is a topical composition having a pH of 3.5 to 4.1, at least 5.0% (w/v) ascorbic acid, an aminosugar, and water. The ascorbic acid may or may not be pretreated. *See*, U.S. Pat. App. Ser. No. 09/997,663 ("*Application*") at 12, line 4 through 31. The composition may be topically therapeutic against inflammatory skin conditions such as rosacea, acne, an inflammatory allergic skin reaction, hypersensitivity, rash or dermatitis. *Id.* at 21, ls. 5-22. The composition may be adapted for use as foundation or as cleanser. *Id.* at 24, ls. 9-14; *Id.*

9-14; *Id.* at 25, ls. 15-16. The composition may be used to treat inflammatory skin conditions such as rosacea, acne, an inflammatory allergic skin reaction, hypersensitivity, rash or dermatitis. *Id.* at 22, line 22 through p. 23, line 3.

Independent claim 18 is a method of treating rosacea or other inflammatory skin affliction. *Id.* The method comprises applying to afflicted skin a composition having at least 5.0 percent (w/v) pre-treated ascorbic acid, at least 10% (s/v) glucosamine or other anti-inflammatory aminosugar and water and having a pH of 3.5 to 4.1. No dependent claims are pending on claim 18.

**Grounds of Rejection To Be Reviewed On Appeal**

Whether claim 18 is unpatentable under 35 U.S.C. § 112, first paragraph, for lack of enablement.

Whether claim 18 is unpatentable under 35 U.S.C. § 112, second paragraph, for being incomplete for omitting essential elements.

Whether claims 1, 5-8, 10-16, 18-19 are unpatentable under 35 U.S.C. § 103 (a) as being unpatentable over *Schinitsky et al.*, U.S. Pat. No. 4,938,969 in view of *Murad*, U.S. Pat. No. 5,804,594, *Herstein*, U.S. Pat. No. 5,902,591 and *Bassford et al.*, U.S. Pat. No. 2,517,276.

Whether claims 1, 5-8, 10-16, 18-19 are unpatentable under 35 U.S.C. § 103 (a) as being unpatentable over *Schinitsky et al.*, US Pat. No. 4,938,969 in view of *Murad*, US Pat. No. 5,804,594, *Darr et al.*, US Pat. No. 5,140,043 and *Bassford et al.*, US Pat. No. 2,517,276.

### **Grouping of Claims**

The claims do not stand or fall together. As discussed in more detail below, claim 18 requires ascorbic acid to be pretreated. However, claim 1 is not limited to a composition containing pretreated ascorbic acid. Pretreatment of the ascorbic acid has been shown to further increase the stability of the claimed topical composition. *Application* at 8, ls. 11-15. When the ascorbic acid is pretreated, the topical composition of the subject invention has additional benefits in that it does not expand, explode, or discolor as a result of heat, changes in atmospheric pressure, or improper storage. *Id.* at 8, ls. 11-22; *Id.* at 13, ls. 17-24. Pretreatment of ascorbic acid also reduces potential skin irritation. *Id.* at 11, ls. 22-30. Pretreatment of the ascorbic acid is an additional limitation clearly not taught or suggested by the prior art. Therefore, the claims on appeal do not stand or fall together.

### **Argument**

#### **I. Rejection of Claim 18 Under 35 U.S.C. § 112, First Paragraph, for Lack of Enablement is Improper.**

Claim 18 stands rejected for lack of enablement. The examiner maintains that "[t]he claims are broad in that they indicated "pretreatment" but do not define the same in the claim." *Office Action Mailed May 11, 2005* at 2. While the examiner agrees that the specification is enabling, he states that the specification is enabling only for the disclosed process of pre-treating the ascorbic acid. According to the examiner, a topical composition comprising ascorbic acid pretreated by other processes is not enabled. *Id.*

Enablement is determined by whether undue experimentation is needed to practice the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Whether experimentation is undue is based on consideration of the following factors: breadth of the claims, nature of the invention, state of the prior art, level of one of ordinary skill, level of predictability in the art, amount of direction provided by the inventor, existence of working examples, quantity of experimentation needed to make or use the invention based on the content of the disclosure. *Id.* It is improper to conclude that a disclosure is not enabling based on an analysis of only one of the above factors while ignoring one or more of the others. *Id.*

One skilled in the art can practice the claimed composition without undue experimentation. The specification clearly defines each of the constituents of the topical composition of Claim 18. *Application* at 7, ls. 9-12; p. 8, line 23 to 9 line 6; p. 12, ls. 3-31; p. 16, ls. 5-12. The specification also teaches that pretreatment of the ascorbic acid provides additional efficacy, storage stability and lowering of skin irritability. *Id.* at 10, ls. 24-26; p.12 ls. 3-7. Pretreatment of ascorbic acid is taught by example as "ascorbic acid which has been dissolved in water at a relatively high temperature forms a concentrated ascorbic acid solution." *Id.* at 8, ls. 3-10; p. 12, ls. 3-25. The temperatures for dissolving the acid in water are taught as 60 to 90 °C. *Id.* No experimentation is needed to make the claimed composition based on teaching of the specification.

The enablement requirement of 35 U.S.C. § 112 is satisfied provided a specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24

(CCPA 1970). The topical composition of claim 18 not only has pretreated ascorbic acid, but also contains at least 5.0% (w/v) ascorbic acid, water, and at least 10% (w/v) glucosamine or other anti-inflammatory aminosugar. The composition must also have a pH from 3.5 to 4.1. The scope of the claim 18 is not a method of topically applying just any composition containing pretreated ascorbic acid. Rather, the scope of claim 18 also includes other constituents and a composition maintained at a particular pH.

The specification of the subject application discloses at least one method of making and using the claimed topical composition that bears a reasonable correlation to the scope of claim 18. *Id.* at 8, ls. 3-10; p. 12, ls. 3-25. Specifically, the specification teaches how to make and use the composition. *Id.* As mentioned above, pretreatment of ascorbic acid is taught in the specification at page 8, lines 3 through 10, and at page 12, lines 3 through 25. Pretreatment is further taught by example at page 13, lines 17 through 24. When the ascorbic acid is pretreated, the topical composition of the subject invention has additional benefits in that it does not expand, explode, or discolor as a result of heat, changes in atmospheric pressure, or improper storage. *Id.* at 8, ls. 11-22; p. 13, ls. 17-24.

Failure to disclose other methods by which the claimed invention may be made does not render a claim invalid under 35 U.S.C. § 112. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533, 3 USPQ2d 1737, 1743 (Fed. Cir.), *cert. denied*, 484 U.S. 954 (1987). Alternative methods of ascorbic acid pretreatment are known to those skilled in the art. For example, U.S. Pat. No. 6,103,267 teaches a pretreatment of ascorbic acid by first mixing it with water-soluble polymer and water. The pretreated ascorbic acid is then mixed with a surface agent to form a



dispersion mixture useful in cosmetics. Notwithstanding the teachings of pretreatment in the prior art, the prior art methods of pretreatment are not taught or suggested in combination with the constituents that make up the topical composition of the present invention. With or without pretreatment of the ascorbic acid, the topical composition of the subject invention is not taught or suggested by the prior art.

In summary, the breadth of the claim 18, the nature of the invention, the amount of direction provided by the inventor, the existence of a working example, the quantity of experimentation needed to make or use the invention based on the content of the disclosure clearly enables the composition of the method of claim 18 - a composition having a particular pH and containing pretreated ascorbic acid, water and glucosamine or other anti-inflammatory sugar. The specification enables claim 18 because one skilled in the art can practice the claimed invention without undue experimentation.

**II. Rejection of Claim 18 Under 35 U.S.C. § 112, Second Paragraph, as Incomplete for Omitting Essential Elements Is Improper.**

Claim 18 is rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential elements and that the omission amounts to a gap between the elements. *Office Action* Mailed May 11, 2005 at 3. According to the examiner, the omitted elements are the process steps by which the ascorbic acid is pretreated as the pretreatment process "appears to be critical to the invention and should be included in the claims." *Id.*

Section 112, second paragraph of the Patent Act states: "The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, second paragraph, contains two

requirements, 1) the claims must be directed to the subject matter that the applicant regards as his or her invention and 2) precision and definiteness. *See, e.g.,* MPEP 2171. If the scope of subject matter embraced by a claim is clear, and if the applicant has not otherwise indicated that he intends that claim to be of a different scope, then the claim does particularly point out and distinctly claim the subject matter which the applicant regards as his invention." *In re Borkowski*, 422 F.2d 904, 909, 164 USPQ 642, 645-46 (CCPA 1970).

Therefore, a rejection under section 112, second paragraph is appropriate only where applicant has stated that the invention is something different from what is defined by the claims. *In re Moore*, 439 F.2d 1232, 1235, 169 U.S.P.Q. 236, 238 (CCPA 1971); *See also*, MPEP 2172. In the absence of evidence to the contrary, the invention set forth in the claims must be presumed to be that which applicants regard as their invention. *Id.*

Furthermore, the content of applicant's specification cannot be used as evidence that the scope of the claims is inconsistent with the subject matter regarded as the invention by applicants. As noted in *In re Ehrreich*, agreement between the claims and the specification, or lack thereof, is properly considered only with respect to section 112, first paragraph and is irrelevant to compliance with the second paragraph of this section. *In re Ehrreich*, 590 F.2d 902, 906, 200 USPQ 504, 508 (CCPA 1979).

Applicant has never defined or discussed its invention as something other than what is defined by the claims. The invention set forth in the claims must be presumed to be that which applicant regards as her invention. *In re Moore*, 439 F.2d at 1235. In light of the forgoing, the rejection under section 112 second paragraph for unclaimed subject matter is improper.

**III. Rejection of the Claims 1, 5-8, 10-16, 18-19 Under 35 U.S.C. § 103 (a) as Unpatentable Over Schinitzky in View Murad, Herstein and Bassford Is Improper.**

Claims 1, 5-8, 10-16, 18-19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Schinitzky, et al.*, U.S. Pat. No. 4,938,969, in view of *Murad*, U.S. Pat. No. 5,804,594, *Herstein*, U.S. Pat. No. 5,902,591, and *Bassford et al*, U.S. Pat. No. 2,517,276. The examiner maintains that the claimed invention, as a whole, would have been prima facie obvious because “every element of the invention has been collectively taught by the combined teachings of the references.” *Office Action Mailed May 11, 2005* at 4. He supports this conclusion by going through the cited prior art references one by one in order to identify one or more elements of the present invention.

However, in his twelve page office action and over the three years of patent prosecution, the examiner has not identified a single teaching or suggestion in the prior art that motivates his combination of references, or suggests a modification of the teaching of *Schinitzky, et al.* in order to arrive at the present invention. As the examiner picks through the prior art to find and match up the elements of the claimed invention, it is only through hindsight motivation that the examiner arrives at the present invention through his combination of references. The examiner has failed to meet his burden of prima facie obviousness because *Schinitzky, et al.* cannot be properly modified or combined with one or more of the other references for lack of the requisite motivation and suggestion.

The determination of obviousness under 35 U.S.C. § 103 is a legal conclusion based on factual evidence. The factual evidence derives from an inquiry into the scope and content of the

prior art, the differences between the prior art and the claimed subject matter and the level of ordinary skill in the art at the time the invention was created. *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 57 U.S. P.Q. 2d 1161 (Fed. Cir. 2000).

While agreeing that there are differences between the prior art and the claimed invention, the examiner writes: "the prior art does not expressly disclose the combination of at least 10% ascorbic acid, non-toxic zinc salt, water and pH of 3.5 to 4.1." *Office Action Mailed May 11, 2005* at 6. But he also maintains that the prior art amply suggests the combination because the prior art discloses: (a) the combination of ascorbic acid and zinc; (b) the use of ascorbic acid up to 20 percent; (c) dissolving ascorbic acid in water at 60 degrees Celsius; and (d) that a pH of 3.5 to 4.1 is preferred to facilitate entry of the acid into the skin. *Id.*

The first problem with the examiner's logic is that the claimed composition is not a combination of ascorbic acid, non-toxic salt and water. Rather, the composition claimed comprises ascorbic acid, aminosugar and water. The second problem is that the prior art fails to teach, suggest, or motivate the combination of references proposed by examiner in order to arrive at the claimed invention.

*Schinitsky, et al.* teach a composition for reducing the depth or intensity of fine wrinkles in skin affected by intrinsic or photo induced aging. The topical composition of *Schinitsky, et al.* requires tyrosine, ascorbic acid and zinc salt. *Schinitsky, et al.* teach that its topical composition is better than the popular tretinoin compositions because tretinoin only stimulates epidermal cells, but does not result in any observable changes in dermis. *U.S. Pat. No. 4,938,969*, at Col. 2, ls. 25-29. *Schinitsky, et al.* teach that a combination of tyrosine (an amino acid), ascorbic acid

and a non-toxic zinc salt when applied to areas showing fine wrinkles (associated with sun or aging) results in a readily perceivable diminution of the fine wrinkle structure. *Id.* at Col. 2, ls. 5-17.

Furthermore, *Schinitsky, et al.* teach that: "[w]hile the mode of action of the present composition is not wholly understood, it is believed that **the ingredients cooperate to stimulate fibroblast proliferation and to promote** their production of collagen and elastin." *Id.* at Col. 2, ls. 11-16. *emphasis added.* *Schinitsky, et al.* teach zinc salt must be combined with tyrosine in a pharmaceutically acceptable vehicle to have such effect. *Id.* at Col. 3, l. 7-Col. 4, l. 32. In the preliminary (double-blind) trial and after 50 subjects had used one or both creams (with and without tyrosine and ascorbic acid), the code identifying the test cream (with tyrosine and ascorbic acid) and control cream (without tyrosine and ascorbic acid) was broken. Of those 50 patients using the test cream (with tyrosine and ascorbic acid), 48 out of 50 subjects had noted "improvement with the test cream in either the first or second week [of a] four week test period." *Id.* at Col. 4, ls. 19-22. No improvement was noted for the control cream, without tyrosine and ascorbic acid. Zinc and tyrosine are not essential ingredients of the claimed compositions in the present application.

*Schinitsky, et al.* teach the combination of tyrosine, ascorbic acid and zinc sulfate to diminish wrinkles. *Schinitsky, et al.*, however, does not teach or suggest a pH for a composition comprising an aminosugar and ascorbic acid. For this, the examiner picks out *Herstein* U.S. Pat. No. 5,902,591.

*Herstein* teaches a two-component system of a powdered ascorbic acid phase and a liquid phase, the liquid phase containing an emulsion having an effective amount of an organoclay material to stabilize the emulsion. Having an organoclay to stabilize it, the pH of the overall component system of *Herstein* is 3.5 to 4.1. While *Herstein* recommends between about 0.1% to about 20% by weight of ascorbic acid in its powder phase, *Herstein* does not teach or suggest a topical composition comprising ascorbic acid, water and an aminosugar.

Most importantly, there is no motivation or suggestion (or reason) provided by *Schinitsky, et al.* or *Herstein* to combine the teaching of the other and arrive at the claimed topical composition. Neither *Schinitsky, et al.* nor *Herstein* suggest the use of an aminosugar. The motivation to combine these references is provided only through the teaching of the specification of the present invention.

Unlike *Herstein*, *Murad*, U.S. Pat. No. 5,809,594, teaches a composition containing a sugar compound. In *Murad*, ascorbic acid must be used in combination with amino acids, at least one transition metal (such as zinc) and sugar. In contrast to *Schinitsky, et al.*, *Murad's* composition preferably has "at least two amino acids selected from the group of proline, lysine, cysteine, and methionine are present, and at least two the transition metal components including zinc, manganese or copper, or mixtures thereof." *Id.* at Col. 3, ls. 45-51. Unlike *Herstein*, *Murad* does not teach or suggest a two-component system or unique stabilizer. Moreover, all of the examples provided by *Murad* are oral formulations, not topical compositions.

*Murad* does not teach or suggest ascorbic acid be used in the absence of at least one transition metal, such as zinc. *Murad* does not teach or suggest a topical composition having a

pH between 3.5 and 4.1. The examiner selects *Herstein* U.S. Pat. No. 5,902,591 for a pH between 3.5 and 4.1. Furthermore, there is no teaching or suggestion in *Schinitsky, et al, Murad* and/or *Herstein* to combine these references in order to arrive at the claimed invention. The motivation for doing so can only be found through the teaching of the present invention.

The Examiner states that “one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the same would facilitate entry of ascorbic acid into the skin and that the combination would be effective in treating or protecting against skin damage due to exposure to the sun. *Office Action Mailed May 11, 2005* at 6. Further, one of ordinary skill in the art would be motivated to prepare the ascorbic acid according to the processing in Bassford with the expectation that the product would sufficiently pure for pharmaceutical purposes.” *Id.*

Keeping in mind Claim 18 is further limited to pretreated ascorbic acid, the Examiner states “*Bassford et al.* disclose a method of purifying ascorbic acid in which one of the steps includes dissolving ascorbic acid in distilled water at 60 degrees Celsius...” *Office Action Mailed May 11, 2005* at 5. *Bassford et al.*, however, does not teach, disclose or suggest a method of treating an inflammatory skin affliction, a composition containing a aminosugar, or a composition at a particular pH. *Bassford et al.* only teaches how to get the ascorbic acid into a purified form that is good enough for a pharmaceutical composition. There is no motivation or suggestion offered by *Bassford et al.*, to combine its purification method with the teachings of *Schinitsky, et al., Murad* and/or *Herstein* to arrive at the method as defined by Claim 18.

Because of the requisite lack of motivation and/or suggestion to modify the composition of *Schinitzky, et al.* (tyrosine, ascorbic acid and zinc salt) by combination of the teachings of *Murad, Herstein* and/or *Bassford et al.*, the examiner has failed to make a prima facie case of obviousness of the claimed invention. The examiner has not met (and cannot meet) his burden. Therefore, the rejection is improper and must be withdrawn.

**IV. Rejection of the Claims 1, 5-8, 10-16, 18-19 Under 35 U.S.C. § 103 (a) as Being Unpatentable Over Schinitzky in View Murad, Darr and Bassford Is Improper.**

Claims 1, 5-8, 10-16, 18-19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Schinitzky, et al.*, U.S. Patent No. 4,938,969, in view of *Murad*, U.S. Patent No. 5,804,594, *Darr et al.*, U.S. Patent No. 5,140,043 and *Bassford et al.* U.S. Patent No. 2,517,276. The examiner maintains that "[t]he difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination of at least 10% of ascorbic acid, aminosugar, water and pH of 3.5 to 4.1. However, the prior art amply suggests the same as the prior art discloses the combination of ascorbic acid and glucosamine, the use of ascorbic acid up to 20% and that a pH of 3.5 and that at pHs of 4.2 and 4.5, a 5% solution of ascorbic acid remained stable." *See Office Action Mailed May 11, 2005*, at 10.

*Darr et al.* do not teach or suggest a composition having an aminosugar. *Darr et al.* also do not teach or suggest pretreatment of ascorbic acid. Indeed, *Darr et al.* teach away from high quantities of ascorbic acid and pH above 3.5.

Specifically, *Darr et al.* teach that "...the pH of the composition is no more than about 3 to 3.5, preferably no more than about 2.5." *See U.S. Pat. No. 5,140,043* at Col. 3, ls. 29-32 *Darr*



also teaches that his invention relates "topical compositions containing L-ascorbic acid (vitamin C) which are stabilized in aqueous solutions by providing a concentration of L-ascorbic acid above about 1% (w/v) and maintaining the pH below about 3.5." *Id.* at Col. 1, ls. 9 to 11. As described, the composition of *Darr et al.* is not stable at a pH of up to 4.5. Furthermore, *Darr et al.* presents data demonstrating a decrease in the amount of ascorbic acid over time at a pH above 4.2. *Id.* at Figure 3. Similarly, the data also demonstrates that there is spectral broadening of the ascorbic acid over time at pH above 4.2. *Id.* at Figures 4 and 5.

There is no teaching or suggestion in the prior art references to combine the teaching of *Darr et al.* (a composition without an aminosugar) with the compounds found in *Schinitsky et al.*, and *Murad* together with the purification of ascorbic acid of *Bassford et al.* and arrive at the claimed invention. Here again, the examiner has not met his burden of prima facie obviousness for lack of the requisite motivation to combine.

To establish a prima facie case of obviousness, there must be a motivation or suggestion to combine the references. The examiner has not pointed to the motivation (or suggestion) as provided by the prior art to combine the teachings of *Schinitsky et al.* and *Murad*, and/or *Darr et al.* together with *Bassford et al.* and arrive at the claimed invention. While the motivation to combine may be found in the prior art references, knowledge of those of skill in the art or from the nature of the problem to be solved, the examiner has not pointed to a single teaching in any of the references that would motivate or suggest the combination. He has not because he cannot. Therefore, the examiner has not met his burden. Hence, this rejection must be withdrawn.

Summary

Appellant respectfully submits that the claimed compositions are enabled by the specification and can be practiced without undue experimentation. Appellant further submits that the examiner has not met his burden under 35 U.S.C. § 103 in making a prima facie case of obviousness.

For all of the foregoing reasons, the rejections of claims are improper and the basis for the rejections erroneous. Reversal of the examiner's rejections is respectfully requested.

Respectfully submitted,

Date:

*January 5, 2006*

By:

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**CLAIMS APPENDIX**

Claim 1: A composition comprising:

at least 10% (w/v) ascorbic acid;

an aminosugar; and

water, wherein the composition has a pH of 3.5 to 4.1.

Claim 5: The composition of claim 1, wherein the aminosugar comprises glucosamine.

Claim 6: The composition of claim 1, further comprising monodehydroascorbic acid.

Claim 7: The composition of claim 1, further comprising an administration form suitable for topical application.

Claim 8: The composition of claim 1, wherein the composition is topically therapeutic against inflammatory skin conditions.

Claim 10: The composition of claim 5, wherein glucosamine is present in the amount of approximately 20% (w/v).

Claim 11: The composition of claim 1, wherein the composition further comprises one or more ingredients selected from the group consisting of (a) one or more antibacterial agents,

(b) one or more dyes, (c) one or more fragrances, (d) one or more surfactants, (e) one or more thickeners, (f) one or more antioxidants, (g) one or more pharmaceutically acceptable carriers, (h) one or more tissue compatible vehicles, (i) one or more humectants, (j) one or more moisturizers, (k) one or more polymers, (l) one or more cross-linking agents, (m) one or more waxes, (n) one or more resins, and (o) any combination of (a) - (n).

Claim 12: The composition of claim 8, wherein the inflammatory skin condition comprises rosacea, acne, an inflammatory allergic skin reaction, hypersensitivity, rash or dermatitis.

Claim 13: The composition of claim 1, wherein the composition is adapted for use as foundation.

Claim 14: The composition of claim 1, wherein the composition is adapted for use as cleanser.

Claim 15: The composition of claim 1, wherein the water is distilled or deionized water.

Claim 16: The composition of claim 1, wherein the composition further comprises one or more ingredients selected from the group consisting of: almond meal, alumina, aluminum oxide, aluminum silicate, apricot seed powder, attapulgite, barley flour, bismuth oxychloride, boron

nitride, calcium carbonate, calcium phosphate, calcium pyrophosphate, calcium sulfate, cellulose, chalk, chitin, clay, corn cob meal, corn cob powder, corn flour, corn meal, corn starch, diatomaceous earth, dicalcium phosphate, dicalcium phosphate dihydrate, fullers earth, hydrated silica, hydroxyapatite, iron oxide, jojoba seed powder, kaolin, magnesium trisilicate, mica, microcrystalline cellulose, montmorillonite, oat bran, oat flour, oatmeal, peach pit powder, pecan shell powder, polybutylene, polyethylene, polyisobutylene, polymethylstyrene, polypropylene, polystyrene, polyurethane, nylon, teflon, polytetrafluoroethylene, polyhalogenated olefins, pumice rice bran, rye flour, cericite, silica, silk, sodium bicarbonate, sodium silicoaluminate, soy flour synthetic hectorite, talc, tin oxide, titanium dioxide, tricalcium phosphate, walnut shell powder, wheat bran, wheat flour, wheat starch, zirconium silicate, or mixtures thereof.

Claim 18: A method of treating rosacea or other inflammatory skin affliction, the method comprising topically applying to the afflicted skin a composition comprising at least 5.0% (w/v) pre-treated ascorbic acid; at least 10% (w/v) glucosamine or other anti-inflammatory aminosugar; and water, wherein the composition has a pH of 3.5 to 4.1.

Claim 19: The composition of claim 13, wherein the composition further comprises one or more ingredients selected from the group consisting of (a) one or more antibacterial agents, (b) one or more dyes, (c) one or more fragrances, (d) one or more surfactants, (e) one or more thickeners, (f) one or more antioxidants and (g) any combination of (a) - (f).

**EVIDENCE APPENDIX**

None.

**RELATED PROCEEDINGS APPENDIX**

None.